STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE SERVICES

Before the Commissioner of Financial and Insurance Services

In the matter of

XXXXX
Petitioner **File No. 86412-001**

v

Blue Care Network of Michigan
Respondent
_____/

Issued and entered
This 8th day of February 2008
by Ken Ross
Acting Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On November 21, 2007, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Services (Commissioner) under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*.

In its November 21, 2007, response to the Commissioner's immediate notice of the request, Blue Care Network of Michigan (BCN) raised the issue of the timeliness of the Petitioner's appeal. Subsequently, BCN agreed that timeliness was not an issue because the Petitioner had contacted BCN on October 1, 2007, to say she had not received the final adverse determination following her step two grievance in August 2007.[1] BCN then mailed a final adverse determination to her in October 2007. Therefore, on December 4, 2007, after a review

[1] It appears from the record that the initial final adverse determination dated August 31, 2007, was sent to the Petitioner's cardiologist who was not her authorized representative.

of the material submitted, the Commissioner accepted the request for external review as complete and timely.

Because the case required analysis by a medical professional, the Commissioner assigned it to an independent review organization (IRO). The IRO submitted its recommendation to the Commissioner on December 18, 2007.

II
FACTUAL BACKGROUND

The Petitioner is a member of BCN, a health maintenance organization (HMO). The BCN 1 Certificate of Coverage (the certificate) and its prescription drug rider PDR-5/10C (the rider) define the Petitioner's benefits.

The Petitioner has a history of type 2 diabetes with poor control. Through her endocrinologist, she requested coverage for the prescription drug Byetta. BCN denied the request.

The Petitioner appealed and BCN maintained its denial. The Petitioner exhausted BCN's internal grievance process and appeals its final adverse determination.

III
ISSUE

Did BCN properly deny the Petitioner authorization and coverage for the prescription drug Byetta?

IV
ANALYSIS

PETITIONER'S ARGUMENT

The Petitioner, on the advice of her endocrinologist, requested coverage for Byetta, an injectible drug used to improve blood sugar control in type 2 diabetics. The Petitioner contends that she receives numerous benefits from taking Byetta instead of insulin. In a letter to the Office of Financial and Insurance Services dated October 22, 2007, she explained the advantages of Byetta, which are summarized here:

- With the addition of Byetta she has better control of her diabetes and may be able to reduce her dose of Metformin or eliminate it altogether. Before taking Byetta she was taking Metformin daily (500 mg in the am and 1000 mg with dinner), a dosage that caused severe gastrointestinal distress and diarrhea.

- Her overall well-being has improved with the addition of Byetta. She has lost 22 pounds, is retaining less water, has less fatigue; and her diabetes and hypertension are under control.

- She is still producing insulin, so she doesn't want to take additional insulin.

- Her endocrinologist has documented her improvement on Byetta and believes her diabetes will continue to improve with the use of Byetta because it controls her sugar very well and prevents complications that come with other drugs (Actos or Avandia) which increase the risk of fluid retention, worsening of blood pressure, and heart disease.

The Petitioner's cardiologist notes that she has done quite well on Byetta and says that "it would be very risky…to take her off [Byetta] given her medical problems and her cardiac history." Her primary care physician wrote, in a letter dated December 10, 2007, to BCN's appeals and grievance:

> [The Petitioner] is currently using Byetta. And is doing very well on it. I feel if she stopped Byetta and started using Insulin her appetite would increase and thus she would eat more food and most likely put on weight. This will not help her general health or her diabetes. I have recommended before in my letters that insulin is a poor option for her medical treatment. [The Petitioner] has insulin resistant diabetes mellitus Type II; she has enough intrinsic insulin. But the insulin present needs to be utilized better. This is why she should continue her present medical regimen. Adding more insulin as [BCN] suggests is not the answer to her medical problems. [The Petitioner] is still losing weight and her diabetes is controlled and I would like this to continue. Since [the Petitioner] has been on Byetta she has been able to stop her Actos and lower her dosage of Metformin ER to Metformin 500mg one tid.

The Petitioner and her physicians believe BCN should provide coverage for Byetta because it is medically necessary for the treatment of her diabetes.

BCN's Argument

In its August 31, 2007, final adverse determination, BCN denied coverage for Byetta, a non-formulary prescription drug, saying, "[The Petitioner] has not completed the step care therapy requirements needed before a non-formulary medication is approved. BCN requires documentation that the member has experienced failure with intensive treatment with Insulin to determine efficacy for type 2 diabetes prior to using Byetta." BCN also believed there were formulary drugs available to treat the Petitioner's condition, i.e., intensive insulin therapy.

BCN says that since Byetta is not on its prescription drug formulary and the Petitioner has not completed the step care therapy requirements to justify the use of Byetta as a non-formulary drug, it is not a covered benefit and its denial was appropriate.

Commissioner's Review

Generally, the Petitioner only has coverage for prescription drugs that are on the BCN formulary and Byetta is not on the formulary. However, the rider recognizes that there are exceptions to the formulary limitation under certain conditions, e.g., a non-formulary prescription drug may be covered if it is medically necessary. The rider defines "covered drug" as:

> a Generic or Brand Name Prescription Drug which is: a) included in and dispensed in accordance with the Health Plan Formulary; b) prescribed by a Plan Provider; and c) obtained through a Participating Pharmacy…. A non-formulary drug is also a Covered Drug when the Plan Provider and Health Plan agree that it is medically necessary and the prescription for the drug is preauthorized. [Emphasis added]

Moreover, there are two provisions in the Insurance Code of 1956 that require exceptions to formulary limitations when non-formulary prescription drugs are medically necessary. The first, of general application, is Section 3406o[2] which says:

[2] MCL 500.3406o.

> An insurer[3] that delivers, issues for delivery, or renews in this state an expense-incurred hospital, medical, or surgical policy or certificate that provides coverage for prescription drugs and limits those benefits to drugs included in a formulary shall do all of the following:
>
> * * *
>
> (c) Provide for exceptions from the formulary limitation when a non-formulary alternative is a medically necessary and appropriate alternative. This subdivision does not prevent an insurer from establishing prior authorization requirements or another process for consideration of coverage or higher cost-sharing for non-formulary alternatives. Notice as to whether or not an exception under this subdivision has been granted shall be given by the insurer within 24 hours after receiving all information necessary to determine whether the exception should be granted. [Emphasis added]

The second provision is in Section 3406p[4] which applies specifically to medication for diabetics like the Petitioner. It says in part:

> An expense-incurred hospital, medical, or surgical policy or certificate delivered or issued for delivery in this state and a health maintenance organization contract that provides outpatient pharmaceutical coverage directly or by rider shall include the following coverage for the treatment of diabetes, if determined to be medically necessary:
>
> * * *
>
> (b) Nonexperimental medication for controlling blood sugar, if prescribed by an allopathic or osteopathic physician. [Emphasis added]

Section 3406p requires an HMO like BCN that provides outpatient pharmaceutical coverage to cover nonexperimental medication for controlling blood sugar when it is medically necessary and prescribed by an allopathic or osteopathic physician. It is uncontroverted in this case that Byetta is a nonexperimental medication for controlling blood sugar and that it was prescribed by an allopathic physician (XXXXX, MD, the Petitioner's endocrinologist). To help the Commissioner resolve the issue of whether Byetta is medically necessary, the matter was assigned to an IRO for the recommendation of an expert.

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[3] Includes health maintenance organizations pursuant to MCL 500.3503.

[4] MCL 500.3406p.

The IRO physician reviewer in this case is board certified in internal medicine and board eligible in endocrinology. The IRO reviewer also holds an academic appointment and has been in practice for more than 15 years. The IRO reviewer recommended reversing BCN's denial of coverage.

The IRO reviewer explained the rationale for the recommendation:

> The MAXIMUS physician consultant noted that prior to starting Byetta, [Petitioner's] HgbA1c was 6.8 on 1/20/07 and 7.0 on 2/28/07. The MAXIMUS physician consultant also noted that after staring Byetta, her HgbA1c was 6.3 on 6/1/07, 9/20/07, and 11/5/07. The MAXIMUS physician consultant further noted that the [the Petitioner's] treating physician reported that her blood sugar went out of control, her HgbA1c increased, and her blood pressure was 150/100 when Byetta was stopped. The MAXIMUS physician consultant indicated that [the Petitioner] reported a 22 pound weight loss with Byetta and that her physician documented a 20 pound weight loss. The MAXIMUS physician consultant also indicated that her HgbA1c declined with Byetta. The MAXIMUS physician consultant explained that [the Petitioner] has improved with Byetta. The MAXIMUS physician consultant also explained that Byetta is indicated for treatment of her condition.

The IRO reviewer concluded that the Petitioner improved with Byetta and that it is medically necessary for the treatment of her condition. The IRO reviewer's recommendation, based on extensive expertise and professional judgment, is afforded deference by the Commissioner. The Commissioner can discern no reason why the IRO reviewer's judgment should be rejected in the present case. Therefore, the Commissioner accepts the IRO reviewer's conclusion that Byetta is medically necessary for the Petitioner at this time.

BCN has argued that the Petitioner must complete step therapy before a non-formulary medication is approved, i.e., she must demonstrate that she has experienced failure with a formulary drug (insulin in this case) before using Byetta. Step therapy is the practice of beginning treatment for a medical condition with the most cost-effective and safest drug therapy and progressing to other more costly or risky therapies only if necessary. The aim of step therapy is to control costs and minimize risks, and there are usually sound medical reasons to

use it. However, while Section 3406o allows for step therapy, it does not require it, and Section 3406p includes no provisions for a carrier to require step therapy for diabetes-related prescription drugs. Moreover, the record is replete with information that establishes that the Petitioner has already tried other medications and her doctors have warned of the risks of insulin therapy.

The IRO reviewer observed that the Petitioner had tried various alternatives (Glipizide, Actos and Metformin) but still had poor control; when her physician added Byetta, her HgbA1c went down. The Commissioner notes that the Petitioner's endocrinologist pointed out the Petitioner's risks when using other medications (Actos and Avandia), and her primary care physician and endocrinologist both were of the opinion that insulin should not be her medical treatment a this time because of the success the Petitioner had achieved with Byetta. The Petitioner's cardiologist said it would be risky to take her off Byetta given her cardiac history.

Therefore, pursuant to Sections 3406o and 3406p and the opinion of the IRO reviewer, the Commissioner finds that Byetta is medically necessary for the Petitioner and BCN is required to cover it as an exception to its formulary limitation.

V
ORDER

BCN's August 31, 2007, final adverse determination is reversed. BCN shall authorize coverage for the Byetta in accordance with the terms and conditions of the prescription drug rider within 60 days of the date of this Order. BCN shall, within seven days of providing coverage, provide the Commissioner proof it has implemented the Commissioner's Order. To enforce this Order, the Petitioner must report any complaint regarding the implementation of this Order to the Office of Financial and Insurance Services, Health Plans Division, toll free 877-999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this

Order in the Circuit Court for the county where the covered person resides or in the Circuit Court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Services, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.